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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,409	12/30/2003	Johanna Jacoba Maria Meulenberg	01-1793-4-C4	4880

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
07/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/750,409	MEULENBERG ET AL.	
	Examiner	Art Unit	
	MYRON G. HILL	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24-26 and 32-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24-26 and 32-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the papers filed 4/28/10.

This action is on claims 21, 22, 24, and 32-37.

Rejections not repeated are withdrawn.

Rejections NEW

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 32 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 32 requires a full length infectious clone that expresses a heterologous Orf7 of ATCC 2332.

The goal of written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed", see In re Barker, 559 F.2d 588, 592 n.4 (CCPA 1977). The inventor has an obligation under "written description" to disclose the technologic knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the invention that is claimed. See

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). In the instant disclosure, Applicants have made statements and more or less a wish list for others to conduct research and make specific clones. Applicant cannot enjoy the fruit of excluding others from practicing the invention for a limited period of time without providing the public meaningful disclosure. See Ariad Pharmaceuticals Inc. v. Eli Lilly & Co., 94 USPQ2d 1161 (Fed. Cir. 2010)

Here, Applicants' teaching does not commensurate with the scope of patent protection. Applicants were not in possession of the construct claimed and the specification does not teach how to make it. The disclosure does not possess what it claims. The specification does not set forth the metes and bounds of that encompass, and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the undisclosed regions where the region may encompass. Thus, the disclosure fails to provide a meaningful disclosure and possession of the scope of the now claimed invention.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 21, 24, and 26 are rejected under 35 U.S.C. 102(b) as anticipated by Wensvoort *et al.* (WO 92/21375).

Applicant argues that Wensvoort *et al.* does not disclose SEQ ID# 18 at the 3 prime end of the genome,

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.*

The term recombinant in claim 26 does not differentiate a recombinant virus from the viral islolate.

Applicants intended use limitations of infectious do not alter the fact that the claims are drawn to nuclic acid constructs, not methods of making infectious virus.

The SEQ ID# 18 at the 3 prime end of the PRRSV genome is an inherent feature of the virus of the deposit which is possessed by Wensvoort *et al.*

Thus, Wensvoort *et al.* anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21, 24-25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al.* (WO 92/21375), Moormann *et al.* (Journal of Virology 1996, Vol 70, pages 763-770).

Applicant argues that prior art would not result in the invention because it does not teach SEQ ID# 18, that the DNA clones are not used in non-permissive cells, and that prior to the instant application, no one made an infectious clone over 12KB.

Applicant's arguments have been fully considered and not found persuasive.

Wensvoort *et al.* in claim 4 describes a vector corresponding to the isolate deposit CNCMI-1102. This vector corresponds to the infectious agent, not the sequence disclosed in Wensvoort *et al.*

The lack of infectious plus stranded RNA clones over 12 KB in the prior art is noted as in para#4. Applicant is asserting 12 KB is too short for PRRSV and thus PRRSV could not be made without SEQ ID# 18 on the terminus. A lack of infectious clones over 12 KB does not teach away from making clones over 12 KB. Applicant or the specification has not provided evidence that at the time of invention clones over 12KB were doomed to fail.

As discussed previously, the prior art makes it clear that full length clones are needed and one of ordinary skill in the art would make full length clones. The argument over infection of non-permissive cells is not in the claims and is an intended use of the DNA sequence.

Thus, the claims are unpatentable over Wensvoort *et al.* and Moormann *et al.*

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wensvoort *et al*. (WO 92/21375), and Moormann *et al*. (Journal of Virology 1996, Vol 70, pages 763-770) as applied to claims 21, 24-25, and 26, further in view of Drew et al.

Applicant argues the above arguments apply to both 103 rejections.

Applicant's arguments have been fully considered and not found persuasive.

The rejection is maintained for reasons discussed above.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648